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| 09/639,453 | 08/15/2000 | Arthur T. Sands | 7705.0002-03 | 3310 |

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[REDACTED] EXAMINER

SANDALS, WILLIAM O

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1636 | [REDACTED] |

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/639,453

Applicant(s)

Sands et al.

Examiner

William Sandals

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 24, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 and 8 is/are pending in the application.

4a) Of the above, claim(s) 8 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on May 24, 2002 is/are accepted or objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: approved disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

*Filed
DFT#12*

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DETAILED ACTION

Status of the Claims

1. Claims 1-6 and 8 are pending. Claim 8 is withdrawn by a previous election to a non-elected group.
2. Claims 1-6 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 19 of copending Application No. 08/728,963, and over claims 1-6 and 28 of copending Application No. 09/570,923.
3. Claims 1 and 2 stand rejected under 35 U.S.C. 102(a) as being anticipated by Gruber et al. The response to arguments presented in Paper No. 10, filed May 24, 2002 follows the repeated rejection below.
4. Claims 1-6 stand rejected under 35 U.S.C. 102(e) as being anticipated by US 5,679,523. The response to arguments presented in Paper No. 10, filed May 24, 2002 follows the repeated rejection below.

Drawings

5. The drawings as submitted on May 24, 2002, have been approved by the draftsman.

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Response to Arguments

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 19 of copending Application No. 08/728,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a library of cultured eukaryotic cells with vectors integrated into a cellular transcript. The claims of 08/728,963 are also drawn to a library of cultured eukaryotic cells with vectors integrated into a cellular transcript. The claims are not identical, but are drawn to patentably indistinguishable subject matter. Thus the claims are subject to an obviousness-type double patenting rejection.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 28 of copending Application No. 09/570,923. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a library of cultured eukaryotic cells with vectors integrated into a cellular transcript. The claims of 09/570,923 are also drawn to a library of cultured eukaryotic cells with vectors integrated into a cellular transcript. The claims are not identical, but are drawn to patentably indistinguishable subject matter. Thus the claims are subject to an obviousness-type double patenting rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. In Paper No. 10, in response to the above rejection, Applicants have expressed an intention to file a terminal disclaimer upon a determination of allowability of the claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Gruber et al.

Gruber et al. taught (see especially the abstract, introduction and figures) a library of cultured eukaryotic cells transfected with vectors which are stably integrated internally to a cellular transcript, and 5' to a cellular transcript. The cells of Gruber et al. are treated with a collection of genomic DNA's and a collection of cDNA's which have been cloned into a library of vectors. The library of vectors is transformed into the cultured cells as recited into the abstract, at three locations in the *nitA* gene in the genome of the cell. The insertions were as shown in Figure 2B, within an exon, or 5' to an exon in a cellular transcript, providing spliced foreign exons into the transcript..

12. Arguments presented in Paper No. 10 assert that the "examiner only proffered a bare conclusion that Gruber et al. teaches a library of cultured eukaryotic cells transfected with vectors which are stably integrated internally to a cellular transcript, and 5' to a cellular transcript", and that there was no attempt to establish that Gruber et al. teaches all of the limitations in the claimed process.

The rejection has been expanded to include more detail on how the teachings of Gruber et al. anticipate the instant claimed invention. The arguments refer to the method as giving patentable distinction to the product. This is not the case. The product-by-process claims are limited by and defined by the process, determination of patentability is based on the product

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itself. The patentability of a product does not depend on its method of production. In re Thorpe, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985). The prior art as taught by Gruber et al. teaches the product, and therefore anticipates the claims.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,679,523.

US 5,679,523 (Li et al.) taught (see especially columns 4 and 7 and the claims) a library of cultured eukaryotic cells transfected, infected or retrotransfected with vectors which are stably integrated internally to a cellular transcript, and 5' to a cellular transcript in a mammal (see column 9 and the claims). At columns 4 and 7 Li et al. describe how the vector is inserted into the transcript to allow spliced inserts both internal to the transcript and 5' to the transcript. Means of integrating the foreign exon into the transcript are described at column 7 which include transfection, infection, and transposition, as for example by a retrovirus.

14. Arguments presented in Paper No. 10 assert that the "examiner only proffered a bare conclusion" that Li et al. taught a library of cultured eukaryotic cells transfected, infected or retrotransfected with vectors which are stably integrated internally to a cellular transcript, and 5'

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to a cellular transcript in a mammal. It is argued that the rejection does not deal with the process limitations.

The rejection has been expanded to include more detail on how the teachings of Li et al. anticipate the instant claimed invention. The arguments refer to the method as giving patentable distinction to the product. This is not the case. The product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985). The prior art as taught by Li et al. teaches the product, and therefore anticipates the claims.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.

Examiner

May 13, 2003

Remy Yucel
REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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